SECTION 6
510(k) SUMMARY (CONT.)

510(k) Notification K 083617

GENERAL INFORMATION

Applicant:
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U.S.A.
Phone: 650-454-0322
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JAN 27 2009

Contact Person:
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Date Prepared: December 6, 2008

Classification:
Breath Nitric Oxide Test System, 21 CFR§862.3080, Class II

Product Code:
MXA

Trade Name:
Apieron INSIGHT™ eNO System

Generic/Common Name:
Breath Nitric Oxide Test System

PREDICATE DEVICE
Apieron INSIGHT™ eNO System (K073265)

INTENDED USE
The intended use of the Apieron INSIGHT™ eNO System is to quantitatively measure exhaled nitric oxide (eNO) in expired human breath as a marker of inflammation in persons with asthma. Measurement of eNO in expired human breath by the Apieron INSIGHT eNO System is a non-invasive, simple and safe method to measure a decrease in eNO in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of the therapeutic effects in patients with elevated eNO levels. The Apieron INSIGHT eNO System is suitable for use in children

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ages 8 to 17 years of age, and in adults 18 years of age and older. eNO measurements, as an adjunct to established clinical assessments, provide the physician an objective marker to evaluate the patient's response to anti-inflammatory therapy. The Apieron INSIGHT eNO System can be used by trained operators in a physician's office laboratory setting. The Apieron INSIGHT eNO System should not be used in critical care, emergency care or in anesthesiology.

PRODUCT DESCRIPTION

The proposed Apieron INSIGHT eNO System consists of a Monitor, a multi-use disposable Sensor Cartridge and the same disposable test supplies as the cleared device. The only difference between the proposed devices and the cleared device is that the single-use disposable eNO Sensor Cartridge of the INSIGHT System has been tested and proven to support up to 10 patient uses and 5 QC tests. A modification has been made to the software which will allow for counting the uses of the Sensor Cartridge and prevention of uses beyond the specified limits. Two sensors are being proposed for clearance one for 10 patient uses and 5 QC tests and one for 5 patient uses and 5 QC tests. The Monitor functions the same and contains the same measurement and breath sampling hardware to provide for a user-friendly interface guiding the operator through the test sequence and the patient through the breath sampling maneuver. The 10-use and the 5-use disposable Sensor Cartridges contain the same Biosensor as in the cleared device which changes its optical transmission properties when it reacts with the nitric oxide in the breath sample. Apart for some software changes to deal with the number of sensor uses, and the addition of more air purges between tests to clear the sensor of nitric oxide from the previous test, the proposed Apieron INSIGHT eNO System is unchanged. It is transportable, operated by an AC outlet and designed for use with the Sensor Cartridge. The proposed Apieron INSIGHT eNO System has the same indication for use as the predicate device, the Apieron INSIGHT eNO System (K073265).

SUBSTANTIAL EQUIVALENCE

The Apieron INSIGHT eNO System is substantially equivalent to the predicate device with regard to function, intended use, and physical characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the proposed Apieron INSIGHT eNO System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the proposed Apieron INSIGHT eNO System to support a determination of substantial equivalence to the predicate device.

SUMMARY

The Apieron INSIGHT eNO System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 27 2009

Apieron, Inc.
c/o Nina Peled, Ph.D., MBA
Vice President, Global Head of Regulatory and Clinical Affairs
155 Jefferson Drive
Menlo Park, CA 94025

Re: k083617
Trade/Device Name: Apieron INSIGHT™ eNO System
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath nitric oxide test system
Regulatory Class: Class II
Product Code: MXA
Dated: December 24, 2008
Received: December 29, 2008

Dear Dr. Peled:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): **K083617**

Device Name: Apieron INSIGHT™ eNO System

Indication For Use:

The intended use of the Apieron INSIGHT™ eNO System is to quantitatively measure exhaled nitric oxide (eNO) in expired human breath as a marker of inflammation in persons with asthma. Measurement of eNO in expired human breath by the Apieron INSIGHT eNO System is a non-invasive, simple and safe method to measure a decrease in eNO in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of the therapeutic effects in patients with elevated eNO levels. The Apieron INSIGHT eNO System is suitable for use in children ages 8 to 17 years of age, and in adults 18 years of age and older. eNO measurements, as an adjunct to established clinical assessments, provide the physician an objective marker to evaluate the patient's response to anti-inflammatory therapy. The Apieron INSIGHT eNO System can be used by trained operators in a physician's office laboratory setting. The Apieron INSIGHT eNO System should not be used in critical care, emergency care or in anesthesiology.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k): **K083617**